

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#42

Application No.: 10/534,725

Filed: May 12, 2005

1<sup>st</sup> Inventor: H. Abe

For: Indole Derivatives as Somatostatin  
Agonists or Antagonists

Atty. Dkt. No. 3122 USOP

Art Unit: tba

Examiner: tba

Allowed:

Batch:

Paper No.:

Information Disclosure Statement

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 23313-1450

Sir:

Pursuant to 37 CFR §1.56, 1.97 and 1.98, Applicants' request consideration of the reference listed on the attached form PTO-1449 under §1.97(b). Copies of foreign patent documents and non-patent literature are enclosed.

This statement is being timely filed before the mailing of a first Office Action on the merits. No fee is required for this filing.

Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, the Examiner is respectfully invited to call Applicants' attorney.

Respectfully submitted,

Dated: July 21, 2005

(847) 383-3391

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Elaine M. Ramesh  
Elaine M. Ramesh, Ph.D., Reg. No. 43,032  
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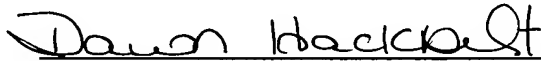
Takeda Pharmaceuticals North America, Inc.  
Intellectual Property Department  
475 Half Day Road  
Lincolnshire, IL 60069 USA

U.S. Patent Application Serial No.: 10/534,725

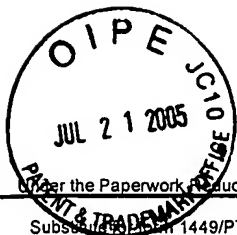
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PTO/SB/08A (08-03)

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Subsection 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/534,725
Filing Date	May 12, 2005
First Named Inventor	H. Abe
Art Unit	tba
Examiner Name	tba
Attorney Docket Number	3122 USOP

Sheet 1 of 3

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US- 2002/00901090	07-11-2002	B. Cole et al.	
		US- 6,329,389	12-11-2001	Takeda Chemical Industries	
		US- 2004/0058877	03-25-2004	Pfizer Inc.	
		US- 6,696,418	02-24-2004	Pfizer Inc.	
		US- 6,025,372	02-15-2000	Merck & Co., Inc.	
		US- 6,057,338	05-02-2000	Merck & Co., Inc.	
		US- 5,773,441	06-30-1998	Eli Lilly and Company	
		US- 2004/0024067	02-05-2004	S. Remiszewski et al.	
		US- 6,387,932	05-14-2002	Merck & Co., Inc.	
		US- 2003/0229200	12-11-2003	L. Chen et al.	
		US- 2003/0195212	10-16-2003	T. Lundstedt et al.	
		US- 2002/0016298	02-07-2002	B. Hay et al.	
		US- 2002/0128206	09-12-2002	B. Hay et al.	
		US- 6,599,795	07-29-2003	Mitsubishi Denki Kabushiki Kaisha	
		US- 6,600,015	07-29-2003	Hoffmann-La Roche Inc.	
		US- 6,552,065	04-22-2003	Novartis AG	
		US-			
		US-			
		US-			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>8</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
		EP 1 086 947	03-28-2001	Pfizer Products Inc.		
		WO 03/042204	05-22-2003	Takeda Chemical Industries		✓
		EP 1 437 351	07-14-2004	Takeda Chemical Industries		
		WO 99/52875	10-21-1999	Takeda Chemical Industries		
		WO 01/25228	04-12-2001	Takeda Chemical Industries		✓
		EP 1 227 090	07-31-2002	Takeda Chemical Industries		

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Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(Use as many sheets as necessary)*

**Complete if Known**

Application Number	10/534,725
Filing Date	May 12, 2005
First Named Inventor	H. Abe
Art Unit	tba
Examiner Name	tba
Attorney Docket Number	3122 US0P

Sheet	2	of	3
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## U. S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	MM-DD-YYYY			
		WO 01/55106	08-02-2001	Melacure Therapeutics AB		
		GB 2 140 423	11-28-1984	Kimberly-Clark Corporation		
		WO 00/26188	03-11-2000	Max-Planck-Gesellschaft		✓
		EP 0 761 220	03-12-1997	Eli Lilly and Company		
		WO 98/44921	10-15-1998	Merck & Co., Inc.		
		WO 98/45285	10-15-1998	Merck & Co., Inc.		

Examiner Signature		Date Considered	
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Sheet	3	of	3
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## U. S. PATENT DOCUMENTS

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		Country Code <sup>3</sup> *Number <sup>4</sup> *Kind Code <sup>5</sup> (if known)	MM-DD-YYYY			
		WO 02/16350	02-28-2002	Takeda Chemical Industries		✓
		WO 01/74844	10-11-2001	F. Hoffmann-La Roche AG		
		WO 02/22577	03-21-2002	Novartis-Erfindungen		
		GB 2 351 733	01-10-2001	Merck & Co., Inc.		
		JP 52-148032	12-08-1977	Sankyo Co., Ltd.		✓
		WO 03/082819	10-09-2003	Nippon Chemiphar Co., Ltd.		✓

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		Application Number	10/534,725		
		Filing Date	May 12, 2005		
		First Named Inventor	H. Abe		
		Art Unit	tba		
		Examiner Name	tba		
Sheet	1	of	1	Attorney Docket Number	3122 USOP

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		D. MALEY, et al., "Expedient Solid-Phase Synthesis of Fluorogenic Protease Substrates Using the 7-Amino-4-Carbamoylmethylcoumarin (ACC) Fluorophore", <u>J. Org. Chem.</u> (2002) Vol. 67, No. 3, pages 910 - 915	
		F. HERNANDEZ, et al., "A Short Synthesis of de-'prenyl'-ardeemin", <u>Tetrahedron Letters</u> 44, (2003), pages 3367 - 3369	
		I. OJIMA, et al., "Design, Synthesis and Sar of RGD Peptide Hybrids as highly Efficient Inhibitors of Platelet Aggregation", <u>Bioorganic &amp; Medicinal Chemistry Letters</u> , (1995), Vol. 5, No. 17, pages 1941 - 1946	
		L. GRAF, et al., "Electrostatic Complementarity within the Substrate-Binding Pocket of Trypsin", <u>Proc. Natl. Acad. Sci. USA</u> , (1988), Vol. 85, pages 4961 - 4965	
		T. TANAKA, et al., "Human Leukocyte Cathepsin G. Subsite Mapping with 4-Nitroanilides, Chemical Modification, and Effect of Possible Cofactors", <u>Biochemistry</u> , (1985), Vol. 24, pages 2040 - 2047	
		J. MACOR, et al., "The Discovery of a Novel and Potent Benzodiazepine Receptor Pharmacophore", <u>Bioorganic &amp; Medicinal Chemistry Letters</u> , Vol. 5, No. 20, pages 2397 - 2402	
		A. VARNAVAS, et al., "Anthranoyl-Anthranilic Acid: A Template for the Development of a New Class of Cholecystokinin Receptor Ligands", <u>Pharmazie</u> , (1996), Vol. 51, No. 10, pages 697 - 700	
		A. BERNHARDT, et al., "The Solid-Phase Synthesis of Side-Chain-Phosphorylated Peptide-4-Nitroanilides", <u>J. Peptide Res.</u> (1997), Vol. 50, Vol. 2, pages 143 - 152	
		M. MERGLER, et al., "Protected Peptide p-nitroanilides by Solid-Phase Synthesis", <u>Letters in Peptide Science</u> , (2000), Vol. 7, No. 1, pages 1 - 7	
		A. ESCHERICH, et al., "Peptide/Benzodiazepine Hybrids as Ligands of CCKa and CCKb Receptors", <u>Biopolymers</u> , (2001), Vol. 56, No. 2, pages 55 - 76	

Examiner Signature		Date Considered	
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

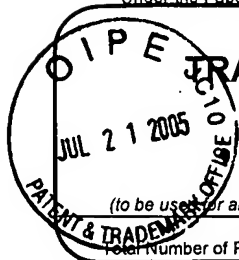
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07-22-05 J06 Rec'd PGT/PTO 21 JUL 2005 PCT

PTO/SB/21 (09-04)

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Total Number of Pages in This Submission

9

Application Number

10/534,725

Filing Date

May 12, 2005

First Named Inventor

H. Abe

Art Unit

tba

Examiner Name

tba

Attorney Docket Number

3122 USOP

### ENCLOSURES (Check all that apply)

☐

Fee Transmittal Form

☐

Fee Attached

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Amendment/Reply

☐

After Final

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Affidavits/declaration(s)

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Extension of Time Request

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Information Disclosure Statement

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Certified Copy of Priority Document(s)

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Reply to Missing Parts/  
Incomplete Application

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under 37 CFR 1.52 or 1.53

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### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

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*Elaine M. Ramesh*

Printed name

Elaine M. Ramesh

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